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1642
PATENT APPLICATION
DOCKET NO.: 0975.1005-006
PT#5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel

Application No.: 09/756,398 Group Art Unit: 1642

Filed: January 8, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS FACTOR

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First-Class-Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>July 5, 2001</u>	<u>Christina M. McSweeney</u>
Date	Signature
<u>Christina M. McSweeney</u>	
Typed or printed name of person signing certificate	

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
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Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. 09/133,119 and Application No. 08/192,093, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.
- ☒ Applicant requests that the following pending applications be considered:

Examiner's
Initials

U.S. Patent Application No. 09/756,161, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-007

U.S. Patent Application No. 09/756,301, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-008

Examiner

Date

- ☒ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: July 5, 2001

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	AB	4,822,776	04/18/89	Cerami et al.	514	21	
	AC	5,658,570	08/19/97	Newman et al.	424	184.1	
	AD	5,750,105	5/12/98	Newman et al.	424	133.1	
	AE	5,231,024	7/27/93	Moeller et al.	435	240.27	
	AF						
	AG						
	AH						
	AI						

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	AL	0212489A2	04 MAR 87	EPO			
	AM	0218868A2	22 APR 87	EPO			
	AN	0288088A2	26 OCT 88	EPO			
	AO	0308378A2	22 MAR 89	EPO			
	AP	0380068A1	01 AUG 90	EPO			
	AQ	0393438A3	24 OCT 90	EPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).					
	AS	Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985).					
	AT	Morrison, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).					

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AL2	0398327A1	22 NOV 90	EPO			
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AN2	0433900A1	26 JUN 91	EPO			
AO2	0526905A2	10 FEB 93	EPO			
AP2	WO91/02078	21 FEB 91	PCT			
AQ2	WO92/07076	30 APR 92	PCT			

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AU	Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. & Biophys. Res. Comm.</i> , 137(2):847-854 (1986).
AV	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).
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AX	Meager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).
AY	Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).
AZ	Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
AR2	Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).
AS2	Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).

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AM3	0260610A2	23 MAR 88	EPO			
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AV2	Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting 1989</i> .
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AT3	Herve, P. et al., "Monoclonal Anti TNF α Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).
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AV3	Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990).
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AX3	Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- α monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).
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AR4	Engelmann, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).
AS4	Verhoef, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," <i>Eur. J. Clin. Microbiol. Dis.</i> , 9(4):247-250 (1990).
AT4	Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).
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AW4	Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).
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AS5	Aderka, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," <i>Israel J. Med. Sci.</i> , 28(2):126-130 (1992).
AT5	Pennington, James, "TNF: Therapeutic Target in Patients with Sepsis," <i>ASM News</i> , 58(9):479-482 (1992).
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AY5	Echtenacher, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," <i>J. of Immunology</i> , 145(11):3762-3766 (1990).
AZ5	Smith, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, <i>Endotoxemia & Sepsis Conference</i> (1991).

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AT6	Genebank Accession, No. M32046 (1990, June 15).
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